

CDER GUIDANCES

NEW/REVISED/WITHDRAWN

01/01/2000 – 12/31/2000

(sorted by date)

Title	Subject	Level at Date of Issue	Publication/ Withdrawal Date	Status
Photosafety Testing	Pharmacology/Toxicology Draft	Level 1	01/10/2000	New
Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products	Generic Drug	Level 1	02/03/2000	New
IND Meetings for Human Drugs and Biologics, Chemistry, Manufacturing, and Controls Information	Chemistry Draft	Level 1	02/04/2000	New
Special Protocol Assessment	Procedural Draft	Level 1	02/09/2000	New
Dissemination of Reprints of Certain Published Original Data	Advertising	Level 1	02/16/2000	Withdrawn
Funded Dissemination of Reference Texts	Advertising	Level 1	02/16/2000	Withdrawn
NDAs: Impurities in Drug Substances	Chemistry	Level 1	02/25/2000	New
Formal Dispute Resolution: Appeals Above the Division Level	Procedural	Level 1	03/07/2000	New
Formal Meetings With Sponsors and Applicants for PDUFA Products	Procedural	Level 1	03/07/2000	New
OTC Treatment of Herpes Labialis with Antiviral Agents	Clinical Medical Draft	Level 1	03/08/2000	New
Conjugated Estrogens, USP: LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence	Biopharmaceutics Draft	Level 1	03/09/2000	New
Content and Format of New Drug Applications and Abbreviated New Drug Applications for Certain Positron Emission Tomography Drug Products	Procedural Draft	Level 1	03/10/2000	New
Information Program on Clinical Trials for Serious or Life-Threatening Diseases: Establishment of a Data Bank	Procedural Draft	Level 1	03/29/2000	New
Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act	Procedural	Level 1	03/30/2000	New
Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research	Clinical Medical Draft	Level 1	03/30/2000	New
Street Drug Alternatives	Compliance	Level 1	04/03/2000	New
E11 Clinical Investigation of Medicinal Products in the Pediatric Population	ICH Draft – Efficacy	Level 1	04/12/2000	New
Q1A(R) Stability Testing of New Drug Substances and Products	ICH Draft – Quality	Level 1	04/21/2000	Revised
Revising ANDA Labeling Following Revision of the RLD Labeling	Generic Drug	Level 2	04/25/2000	New
Major, Minor, Facsimile, and Telephone Amendments to Original Abbreviated New Drug Applications (Revised)	Generic Drug	Level 2	05/01/2000	New
Clinical Evaluation of Drugs to Prevent Dental Caries	Clinical Medical	Level 1	05/18/2000	Withdrawn
Clinical Evaluation of Drugs to Prevent, Control and/or Treat Periodontal Disease	Clinical Medical	Level 1	05/18/2000	Withdrawn
Female Sexual Dysfunction: Clinical Development of Drug	Clinical Medical Draft	Level 1	05/19/2000	New

Products for Treatment				
Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis	Clinical Medical Draft	Level 1	06/14/2000	New
Pediatric Oncology Studies in Response to a Written Request	Clinical Medical Draft	Level 1	06/21/2000	New
Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biologics	Labeling Draft	Level 1	06/21/2000	New
Allergic Rhinitis: Clinical Development Programs for Drug Products	Clinical Medical Draft	Level 1	06/21/2000	Revised
Chronic Cutaneous Ulcer and Burn Wounds – Developing Products for Treatment	Clinical Medical Draft	Level 1	06/28/2000	New
Combined Oral Contraceptives – Labeling for Healthcare Providers and Patients	Labeling Draft	Level 1	07/10/2000	New
Q3B(R) Impurities in New Drug Products	ICH Draft - Quality	Level 1	07/19/2000	Revised
Q3A(R) Impurities in New Drug Substances	ICH Draft - Quality	Level 1	07/20/2000	Revised
Developing Medical Imaging Drugs and Biologics	Clinical Medical Draft	Level 1	07/31/2000	Revised
Q7A Good Manufacturing Practice for Active Pharmaceutical Ingredients	ICH Draft - Quality	Level 1	08/01/2000	New
OTC Treatment of Hypercholesterolemia	OTC	Level 1	08/03/2000	Withdrawn
S7 Safety Pharmacology Studies for Human Pharmaceuticals	ICH Draft – Safety	Level 1	08/07/2000	New
E12A Principles for Clinical Evaluation of New Antihypertensive Drugs	ICH – Efficacy Draft	Level 1	08/09/2000	New
Botanical Drug Products	Chemistry Draft	Level 1	08/11/2000	New
M4 Common Technical Document	ICH Joint Safety/Efficacy (Multidisciplinary) Draft	Level 1	08/24/2000	New
Analytical Procedures and Methods Validation: Chemistry, Manufacturing and Controls Documentation	Chemistry Draft	Level 1	08/30/2000	New
Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Based on a Biopharmaceutical Classification System	Biopharmaceutics	Level 1	08/31/2000	New
Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications	Labeling Draft	Level 1	10/26/2000	New
Submitting and Reviewing Complete Responses to Clinical Holds	User Fees	Level 1	10/26/2000	Revised
Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations	Biopharmaceutics	Level 1	10/27/2000	New
Carcinogenicity Study Protocol Submissions	Pharmacology/Toxicology Draft	Level 1	11/07/2000	New
Cancer Drug and Biological Products – Clinical Data in Marketing Applications	Clinical/Medical Draft	Level 1	11/09/2000	New
Bupirone Hydrochloride Tablets in Vivo Bioequivalence	Biopharmaceutics	*	11/30/2000	Withdrawn
Cimetidine Tablets in Vivo Bioequivalence and in Vitro Dissolution	Biopharmaceutics	*	11/30/2000	Withdrawn
Diclofenac Sodium (tablets) in Vivo Bioequivalence and in Vitro Dissolution Testing	Biopharmaceutics	*	11/30/2000	Withdrawn
Glipizide in Vivo Bioequivalence and in Vitro Dissolution Testing	Biopharmaceutics	*	11/30/2000	Withdrawn
Glyburide in Vivo Bioequivalence and in Vitro Dissolution Testing	Biopharmaceutics	*	11/30/2000	Withdrawn
Oral Extended (Controlled) Release Dosage Forms in Vivo Bioequivalence and in Vitro Dissolution Testing	Biopharmaceutics	*	11/30/2000	Withdrawn
Statistical Procedures for Bioequivalence Studies Using a Standard Two-Treatment Crossover Design	Biopharmaceutics	*	11/30/2000	Withdrawn
Recommendations for Complying With the Pediatric Rule	Clinical Medical Draft	Level 1	12/04/2000	New

Alternate Source of Active Pharmaceutical Ingredients in Pending ANDAs	Generics	Level 2	12/12/2000	New
E11 Clinical Investigation of Medicinal Products in the Pediatric Population	ICH – Efficacy	Level 1	12/15/2000	New
Labeling OTC Human Drug Products – Submitting Requests for Exemptions and Deferrals	OTC Draft	Level 1	12/19/2000	New
Labeling OTC Human Drug Products Using a Column Format	OTC	Level 1	12/19/2000	New
Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products; Chemical Substances	ICH – Quality	Level 1	12/29/2000	New

*No level designated. Guidance published before implementation of the Agency's good guidance practices policy in February 1997.